

Office of Graduate Studies  
University of South Florida  
Tampa, Florida

**CERTIFICATE OF APPROVAL**

Master's Thesis

This is to certify that the Master's Thesis of

**ROSE M. BELL**

with a major in Nursing has been approved  
for the thesis requirement on March 20, 2000  
for the Master of Science degree.

Examining Committee:

Susan C. McMillan  
Major Professor: Susan C. McMillan, Ph.D., ARNP, FAAN

Cecile A. Lengacher  
Member: Cecile Lengacher, RN, Ph.D.

Sandra Holley  
Member: Sandra Holley, Ph.D., ARNP, AOCN

DIGITAL QUALITY INDEXED 4

20000627 183

## REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED THESIS	
4. TITLE AND SUBTITLE THE USE OF CONTEMPORARY THERAPIES IN VETERANS RECEIVING TREATMENT FOR CANCER			5. FUNDING NUMBERS
6. AUTHOR(S) CAPT BELL ROSE M			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) UNIVERSITY OF SOUTH FLORIDA			8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) THE DEPARTMENT OF THE AIR FORCE AFIT/CIA, BLDG 125 2950 P STREET WPAFB OH 45433			10. SPONSORING/MONITORING AGENCY REPORT NUMBER  FY 00 - 207
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION AVAILABILITY STATEMENT Unlimited distribution In Accordance With AFI 35-205/AFIT Sup 1		12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words)			
<b>DISTRIBUTION STATEMENT A</b> Approved for Public Release Distribution Unlimited			
14. SUBJECT TERMS			15. NUMBER OF PAGES
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

THE USE OF COMPLEMENTARY THERAPIES IN VETERANS  
RECEIVING TREATMENT FOR CANCER

by

ROSE M. BELL

A thesis submitted in partial fulfillment  
of the requirements for the degree of  
Master of Science  
Department of Nursing  
College of Nursing  
University of South Florida

May 2000

Major Professor: Susan C. McMillan, Ph.D., ARNP, FAAN

## Table of Contents

<b>List of Tables</b>	<b>iii</b>
<b>Abstract</b>	<b>v</b>
<b>Chapter I. Introduction</b>	<b>1</b>
Statement of the Problem	4
Research Questions	4
Definition of Terms	5
Significance to Nursing	5
<b>Chapter II. Review of the Literature</b>	<b>6</b>
Theoretical Framework	6
The Use of Complementary Therapies	7
Complementary Therapy and Pediatrics	8
Complementary Therapy in Other Types of Cancer	11
Educating Patients on Complementary Therapy	9
Complementary Therapy and Breast Cancer	9
Summary	13
<b>Chapter III. Methods</b>	<b>16</b>
Sample	16
Instrumentation	17
Complementary Therapy Scale	17
Validity	17
Reliability	18
Demographic Data Form	18
Institutional Approval	18
Procedures	18
Data Analysis	19
<b>Chapter IV. Results, Discussion and Conclusions</b>	<b>20</b>
Results	20
Sample	20
Intent to Use Items	23
Current Patterns of Use	25
Relationships with Demographic Variables	26
Overall Intent Scores	26
Other Findings	26

Discussion	27
Sample	27
Intent to Use Scores	29
Relationships with Demographic Variables	29
Overall Intent Scores	30
Other Findings	30
Conclusions	32
References	34
Appendices	36
Appendix A: Complementary Therapy Rating Scale	37
Appendix B: Demographic Data Form	39
Appendix C: Veteran's Administration Approval Letter	40
Appendix D: IRB Approval Letter	41
Appendix E: Consent Form	42

## List of Tables

Table 1	Means, Standard Deviations and Ranges for Demographic Variables	20
Table 2	Frequency and Percent of Subjects by Type of Cancer	21
Table 3	Frequency and Percent of Subjects by Medical Treatments Received	22
Table 4	Frequency and Percent of Subjects by Type of Community	22
Table 5	Frequency and Percent of Responses to Items on the Complementary Therapy Rating Scale	22
Table 6	Current Patterns of Use	25
Table 7	Other Complementary Therapies Identified	27

THE USE OF COMPLEMENTARY THERAPIES IN VETERANS  
RECEIVING TREATMENT FOR CANCER

by

ROSE M. BELL

*An Abstract*

of a thesis submitted in partial fulfillment  
of the requirements for the degree of  
Master of Science  
Department of Nursing  
College of Nursing  
University of South Florida

May 2000

Major Professor: Susan C. McMillan, Ph.D., ARNP, FAAN

The use of complementary therapies in veterans with cancer who are undergoing treatment has been understudied in the literature. The purpose of this study was to identify patterns of complementary therapy use in veterans who received either chemotherapy, radiation therapy, a combination of chemotherapy and radiation or biotherapy treatment for cancer. This descriptive study consisted of a convenience sample of 30 outpatient adult cancer patients, recruited from a local veteran's hospital. The Complementary Rating Scale (TCRS) was used to determine the use of various methods of complementary therapy. This instrument consisted of 14 items that were rated on a Likert-type scale. The scale also utilized an open-ended question designed to explore other complementary therapies used that were not identified on the scale. Patients were approached in waiting areas before their scheduled therapy. Coded surveys were used to ensure patient confidentiality.

Results revealed that vitamins, the most frequently used item, were identified by 76.7% (n=23) of veterans. This was followed by music, (70%, n=21), and prayer, (70%, n=21). Higher education level was significantly related to increased use of prayer ( $r = -.406$ ,  $p=.029$ ), use of vitamins ( $r = -.377$ ,  $p = .044$ ), and use of herbs or other health food items ( $r = -.394$ ,  $p=.035$ ). Twenty-eight of the 30 patients (93.3%) reported using more than one type of complementary therapy. This demonstrated that a higher likelihood existed of using more than one therapy versus a single therapy alone. There were several other therapies cited in the qualitative question about use of other items not listed on the scale. The other category of included items, they felt were helpful for them, were

defined by the patient as hobbies, sports, individual exercise and four that listed spousal support as therapies.

Nursing's awareness of the most current and common complementary therapies used has become increasing important. Nurses need to be aware of the most common therapies as well as the patient populations most likely to be interested in their usage. This information is vital in providing accurate, honest information and the best nursing and holistic care for each individual patient.

Abstract Approved: Susan C. McMillan  
Major Professor: Susan C. McMillan, Ph.D., ARNP, FAAN  
Professor, Department of Nursing

Date Approved: 3/23/00

## Chapter I

### Introduction

Approximately one million new cancer cases were diagnosed in the United States in 1999. Currently, one in four deaths in this country are cancer related, making cancer the second leading cause of death. This cancer statistic has resulted in \$107 billion dollars in estimated annual costs for medical, morbidity and mortality expenses caused by cancer. In addition to the current statistics for cancer treatment, it is estimated today that there are 8 million American cancer survivors in the United States (American Cancer Society [ACS, 1999] ). The continuum of cancer from early diagnosis through survivorship is associated with periods of uncertainty and fear of recurrence. The ultimate goal for many is the desire to maximize longevity with good quality to their lives, control over their own health and the freedom to exercise every reasonable option to promote cure. Commonly, the search for information to achieve these goals leads consumers to the growing wealth of information on complementary and alternative therapies.

Complementary and alternative therapies, sometimes described as complementary and alternative medicine (CAM), have many similar and overlapping mechanisms of action and effect between categories of alternative or complementary therapies (Fernandez, Stutzer, MacWilliam & Fryer, 1998). The term alternative, however, is defined to mean instead of traditional medicine whereas complementary is used in addition to standard therapy (Spiegel, Stroud & Fyfe, 1998). Whether used instead of or in addition to

traditional therapy, these therapy choices can be extensive and commonly include forms such as herbs, massage, relaxation, vitamins and diet.

Information on complementary and alternative therapies has received mainstream acceptance in the media, books, magazines, and the Internet. As a result, they are rapidly gaining global popularity (Cassileth et al., 1995). One study estimated that one in three people in the United States used some form of unconventional therapy in 1990 (Eisenberg, Kessler, Foster, Norlock, Calkins, & DelBanco, 1993). In 1990, Americans spent 13.8 billion dollars on complementary care (Spiegel et al., 1998).

Perhaps these therapies are utilized as a means to control symptoms, complement traditional therapy, improve quality of life or for any host of reasons not satisfied by traditional medicine. For example, a study conducted by Crocetti et al. (1998) reported that 20.5% of their sample used psychological distress as the rationale for use of complementary therapy. Health care consumers often seek second opinions regarding medical treatment but also seek information on alternative therapy, relief of symptoms, enhancement of well-being and promotion of wellness (Cassileth et al., 1995).

Regardless of the rationale, these therapies have grown into a multi-billion dollar business and have “infiltrated every aspect of healthcare” (Cassileth et al., 1995, p.1027). It is for this reason, the oncology or healthcare community can no longer ignore use of these therapies.

Patients and family members often identify the physician as a key resource in information about their health (Lerner & Kennedy, 1992). Yet, one study reported that in an average appointment of approximately 15 minutes, the physician actually spent 1.3 minutes or less providing the patient with information (Lerner et al., 1992). This often

does not allow the time needed to discuss the patient's use or the intent to use complementary therapies.

One of the most concerning statistics of several studies, was that three of every four surveyed did not report this use to their primary care provider (Spiegel, Stroud & Fife, 1998, Eisenberg et al., 1993). According to an editorial by Herbert (1997), patients report some of the reasons for their reluctance to report as being "dismissed or derided, ungrateful, unrealistic or gullible" (p179). Out of the patients that did report their use, approximately 40% of the physicians expressed their disapproval and 4% refused to treat the patients if they continued to use these therapies.

In 1996, herb sales in the United States reached or exceeded 12 billion dollars (Spaulding-Albright, 1997). Spaulding-Albright (1997) reported a survey in which 63% of the 1,008 adults polled would use some combination of herbs in their daily regimen within the next five years. The growing concern is twofold. Not only are a growing number of cancer patients utilizing some forms of complementary therapy but they are utilizing these therapies during conventional treatment while minimizing discussion with their healthcare team. A recent study by Crocetti et al. (1998), examined breast cancer patients' use of complementary and alternative therapies while undergoing traditional medical treatment. Use of these therapies, independent of medical treatment, was reported at 30.2%. Eisenberg et al. (1993) suggested that the number of Americans who may be using unsupervised, unconventional therapies could be as high as 20 million and that the use of these methods is not exclusive to culture or sex. Lerner and Kennedy (1992), also reported a correlation between use and education in persons with cancer, but found women used CAM slightly more often than men. The most common overall users

are described as non-black, with some college education and income above \$35,000 (Eisenberg et al., 1993). Because of the growing popularity and patterns of use, it is imperative that the medical community understands the use of these therapies. It is also important that the reasons for their use are understood so patients will receive the best holistic care, information and treatment approach for their patients with cancer.

#### *Statement of the Problem*

There are a number of studies that address patient use of complementary therapy (Risberg, Wist, Kaasa & Melsom, 1997; Risberg, Lund, Wist, Kaasa & Wilsgaard, 1998; Sollner, Zingg-Schir, Rumpold & Fritsch, 1997) and their patterns of usage (Arakawa, 1997; Brown & Carney, 1996; Crocetti et al., 1997; Fernandez, Stutzer, MacWilliam and Fryer, 1998; Risberg, Lund, Wist, Kaasa & Wilsgaard, 1998). There is however, limited data on complementary therapies and instruments to assess the usage and interest in veterans receiving treatment for cancer. The purpose of this study is to identify the prevalence and types of therapies used in veterans undergoing treatment for cancer.

#### *Research Questions*

The following research questions were addressed in this study:

1. What are the types of complementary therapies used most frequently by veterans being treated for cancer?
2. Is there a relationship between the use of complementary therapies and age or education in veterans being treated for cancer?
3. What is the overall intent to use complementary therapies in veterans being treated for cancer?

### *Definition of Terms*

The following terms are defined for purposes of this study:

*Complementary therapy* is defined as the use of support groups, humor, hypnosis, massage, chiropractic services, acupuncture, relaxation, visualization, prayer, vitamins, herbs, health foods, diet changes and exercise in addition to conventional medical treatment (Bennett & Lengacher, 1998).

*Alternative therapy* is defined as the use of support groups, humor, hypnosis, massage, chiropractic services, acupuncture, relaxation, visualization, prayer, vitamins, herbs, health foods, diet changes and exercise that are intended to replace conventional medical treatment (Bennett & Lengacher, 1998).

### *Significance to Nursing*

The use of complementary therapies has significant implications for nursing. Clinicians who provide care to patients who are undergoing treatment for cancer are often faced with managing side effects, laboratory values, research information and emotional issues on a daily basis. These same clinicians may not be aware of the complementary practices a patient may employ independent of the standard treatment plan. The unreported or under-reported use of complementary therapies during treatment could potentially alter side effects, enrollment and continuance of research, research results, quality of life surveys and survival. Nurses need to be informed of the most current and common complementary therapies used and patient interest in usage in order to provide accurate information and the best medical and holistic care for each individual patient. Results of this study may assist nurses in further understanding the types, frequency and usage of complementary therapies in persons receiving treatment for cancer.

## Chapter II

### Review of The Literature

This chapter includes Ajzen's Theory of Planned Behavior (1980), a behavioral theory, to guide this study. Second, this chapter includes a review of studies related to complementary therapy, pattern and reasons for use in both pediatric and adult oncology patients. Finally, a summary of the research with recommendations for future research are discussed.

#### *Theoretical Framework*

One of the central factors in Ajzen's theory (1980) is a person's intention to engage in a specific behavior. The theory proposes that the stronger the intention to engage in a specific behavior, the more likely they are to perform this behavior. This behavior can be affected by a culmination of lifetime experiences and can be greatly affected by the presence of an immediate situation such as cancer. The Complementary Therapy Rating Scale (CTRS) is intended to measure the intention and actual use of complementary therapy during the cancer treatment experience. The scale was used in an attempt to predict actual or the likelihood of future use.

Further, the theory states, that a person can only decide to perform or not perform a behavior if they are able to perform at will. This factor, accompanied by availability, actual control over a behavior, ability and motivation are included in the perceived control and actual performance of a behavior. A diagnosis of cancer may be a factor that motivates a person to engage in complementary therapy as a readily available form of

control over the behavior and perhaps the illness itself. Conversely, cancer, accompanied by a specific type of treatment or a decreased quality of life, may inhibit a person's use of complementary therapies.

### *The Use of Complementary Therapies*

Risberg, Bremnes, Wist, Kaasa and Jacobsen (1997) conducted a large quantitative study of 252 oncology patients in Northern Norway. This longitudinal study examined patient attitudes about their disease, satisfaction with treatment and its correlation with the use of non-proven therapies and mental distress. The aim of the study was to determine if patient attitudes to information given about their cancer and satisfaction with treatment influenced their use of non-proven therapies and their mental distress. A 5-item modification (GHQ5) of a 20-item general health questionnaire was administered with a follow up questionnaire given 4 months after the first. There was no reliability or validity data available but the scale was reviewed by psychiatric experts for content. This questionnaire was utilized to assess usage of non-proven therapies, mental distress, satisfaction with disease and treatment information as well as quality of treatment and decision making. Multivariate analyses were done by logistic regression analyses after dichotomizing the answer categories. The results indicated that the patients with higher mental distress wanted less information, ( $p=0.05$ ) and reported less satisfaction with the quality information they did receive and less satisfaction with their care. Age was a significant factor in desire for more comprehensive medical information. Patients under the age of 45 desired more information than did older patients (83% versus 52%,  $p=0.001$ ). Education was also a determinant in satisfaction and use of complementary therapy. Patients with better education were more satisfied with information provided by

their practitioner ( $p=0.05$ ) and the local hospital ( $p=0.02$ ). Overall, the study reported that users of complementary therapies did not feel that they were receiving the best treatment possible ( $p=0.04$ ).

#### *Complementary Therapy and Pediatrics*

There was a large study on the use of complementary therapies involving 583 pediatric patients and families in British Columbia by Fernandez, Stutzer, MacWilliam and Fryer (1998). The purpose of this study was to determine prevalence and factors that influenced usage of complementary therapies in this under studied patient population. This quantitative study employed a 27-item questionnaire with yes/no answers and Likert-type scales to determine patterns of use and reasons for the use of complementary therapies in pediatric cancer patients. Three experts, one each in design, patient/family education and complementary therapy were employed to review for content validity. In addition, a pilot study was accomplished with five families. The distribution of chi square probability was used to test for associations between variables and use or nonuse of complementary therapies. Descriptive statistics were used to assess parental perceptions and describe reasons for use and nonuse. The study reported that 67% of the parents did not use any complementary therapies before their child was diagnosed with cancer. Results found that parents with postsecondary education, were more likely to use complementary therapy ( $p<.003$  for mothers and  $p<.006$  for fathers). The study also reported that 156 of 366 patients used complementary therapy and that 68% began while on therapy. Approximately half of those (51%), who used complementary therapies, used both alternative and complementary therapies. The two most common reasons for use were the parents' desire to explore all possible options for their child and to boost the

child's immune system. The two most common reasons for non-use were that the parent was unaware of complementary therapies and that they might interfere with conventional therapies.

#### *Educating Patients on Complementary Therapy*

Strategies to inform people about complementary therapies have also been studied, sometimes with great criticism. Gray et al. (1998) surveyed 634 Canadian individuals who purchased an informational book, which the authors developed on unconventional therapy. This quantitative survey was based on a 10 point scale and some open ended questions about the book's usefulness and relevant information. This study reported a great deal of resistance from colleagues and anger for its undertaking. They feared disastrous results because of its controversial subject. Political pressures were apparent and the book was withdrawn from the patient library. There was no reliability or validity reported for the instrument used. This study reported that 41% of health care providers found the book more helpful than the survivors  $<0.001$ . In addition, 41% of the books purchased were by health care providers, 37% who had cancer and 24% who had at least one immediate family member with cancer.

#### *Complementary Therapy and Breast Cancer*

Two studies of complementary therapies have focused on women with breast cancer. A qualitative study conducted by Brown and Carney (1996) explored the perceptions of health, illness and medical care in 20 breast cancer patients. The participants in this study were divided in two groups. The first group (n=11) received conventional therapy only while the second group (n=9) received conventional therapy combined with alternative therapy. To further compare both groups, time since diagnosis

and/or recurrence was determined. Four of the 20 experienced recurrence and all were in the unconventional group. The participant information was obtained using a semi-structured interview format with open-ended questions. Two reviewers independently coded themes elicited using open and axial coding techniques until saturation was reached. The results of this study identified two major differences between the groups. The unproven therapies group believed that they should receive empathy from the MD and relief of their symptoms. They had an overall holistic view of their care that evolved since their diagnosis of cancer. The conventional therapy group wanted guidance and confirmation that nothing was wrong and their beliefs were lifelong, based on family or religious background. The study, as a result of this research, makes the following recommendations for clinicians. They felt that taking time with the patient to discuss issues such as their perceived gain from treatment, understanding of illness and role expectations from their clinician was vital to a better understanding of the patient's cancer experience.

In a large Italian study by Crocetti et al. (1998), 242 breast cancer patients were questioned about their use of complementary therapy. The aim of this study was to examine patterns of use in female breast cancer patients diagnosed in 1991, who were receiving conventional therapy to include surgery. The instrument was not addressed and the users versus non-users were evaluated using the distribution of chi square probability. A univariate analysis of the variables revealed users to be better educated, younger and married. Only 40 (16.5%) reported any use of complementary therapies after cancer diagnosis while 21 (8.7%) had used these treatments only before. Most interesting, was that 30.2% of the patients used complementary therapy independent of conventional

treatment, 30.2% after conventional treatment and 17% concurrently with their medical treatment. One of the other results of interest was the change in therapies before and after cancer diagnosis. The most common therapies reported after cancer were homeopathy, manual healing, herbalism and acupuncture. The most common therapies reported before cancer include acupuncture, herbalism and homeopathy. Of the patients who reported use, 61.5% reported use for physical distress, 20.5% reported use for psychological distress, 5.1% because of pressure from relatives and 12.8% for other motivations.

#### *Complementary Therapy in Other Types of Cancer*

Three studies examined complementary therapies in patients with other types of cancer. Sollner, Zingg-Schir, Rumpold and Fritsch (1997) examined use of complementary therapy in 215 melanoma patients in a three month period. They were concerned about use of alternative therapies as well as psychological distress, compliance with therapy and the availability of emotional support. The study used a self-developed questionnaire to record patient interest in use, the Horn Heide questionnaire to measure distress and emotional support and the Frieburg questionnaire of coping with illness. The Cronbach alpha reported for Horn Heide was .89 and for the Frieburg .70. The study reported results indicating that the patient/MD relationship was crucial to the use of unproven therapies. Patients more likely to use therapies had a more active coping style ( $p=.001$ ) In addition, the patients were more active, younger 41.3-46.5 vs 48.7-56,  $p<.001$ , had a problem oriented coping style and more often looked toward religion and personal meaning in their disease. Conclusions note that patients in this study consider complementary therapy as a supplement to standard medical treatment as a means of avoiding passiveness of treatment and feelings of hopelessness. Of the patients who

reported the use of complementary therapy, 77% reported using more than one therapy and up to four modalities. Usage was reported as 9.6% in stage one but increased to 61.1% in patients with locoregional disease or distant metastasis. Also noted was that 77% of those who used these therapies used more than one and in advanced disease metabolic or diet therapies were more common.

In a study conducted at the University of Tromso in Norway, Risberg et al. (1997) surveyed 252 cancer patients on arrival, as well as at 4,12, 24 and 60 month intervals to assess attitudes and use of complementary therapies. It also examined how this usage changes during the life of the cancer patient as well as patient opinions of the cause or causes of their cancer. A questionnaire was devised to use for telephone interview to validate user/non user status. Also employed was the General Health Questionnaire to estimate mental distress and a Quality of Life Survey. There was no validity or reliability results reported on any scale. Cox's proportional hazards regression was used to assess impact on survival adjusted for the use of nonproven therapy. Of the 252 patients, 173 returned the survey for a compliance of 69%. During the five-year study period, 40% had used complementary therapy one or more times. Of the total, 74% of complementary therapies used spiritual forms alone or in combination with nonspiritual forms. The cumulative risk reported for using nonproven therapy was 45% over five years and the majority of users started their use in the first three months after diagnosis or during the first four months of treatment.

Another Norwegian study was conducted with 682 patients, Risberg et al. (1997), and evaluating the use of nonproven complementary therapies in cancer patients in Norway. The instrument was an expanded version of a questionnaire originally developed

at the University of Tromso. A pilot study of 31 patients was subsequently conducted for validity but no reliability or validity data was reported. Results were evaluated using chi square test and logistical regression. Results revealed that while 300 of 611 patients felt that closer cooperation between oncologists and complementary therapy practitioners would be important, 173 saw no value. An interesting result of this study was that 67% of the users and 34% of the nonusers believed that complementary therapy practitioners possessed knowledge that was useful in the treatment of cancer. Additionally, 63% of the users and 38% of nonusers reported that they had a positive attitude toward complementary therapy being offered in hospitals. Of the most common reasons for use, 33% reported a belief in the method taken or advised by others. There was a reported 73% still using some forms of complementary therapy, 20% reported prior lifetime use and 27% ended their use.

#### *Summary*

The review of the literature has addressed the areas of research pertinent to complementary therapy use in cancer patients. The review has included international studies as well as various age specific studies for a more comprehensive review of the scope of the problem. These studies suggest that complementary therapies exist and that there is a need for the education of health care professionals. The studies also identify that these practices are not age specific but are common practice among cancer patients of all ages.

A running theme throughout the literature identifies higher level of education as a significant indicator in the usage of complementary therapy (Allen, Neuman & Souhami, 1997; Crocetti et al., 1998; Fernandez et al., 1998; Risberg et al., 1997). Studies also

identify those who are most likely to use complementary therapies also tend to younger than 50 (Crocetti et al., 1998; Loge, Abrahamsen, Ekeberg, Hannisdal & Kaasa, 1997; Risberg et al., 1997; Sollner et al., 1997). This identifies a target population for teaching, conducting studies and interventions. The continual theme of a need for increased medical involvement in complementary therapy in both knowledge and medical research has been identified from this review (Brown & Carney, 1996; Risberg et al., 1997). Because there appear to be many gaps identified between traditional medicine and complementary therapy, more studies are needed to examine current medical programs, barriers and knowledge deficits in the medical community. As the study by Risberg et al., 1997 implies, perhaps more studies on the effectiveness of incorporating both conventional and nonconventional therapy into the treatment of the cancer patient are needed.

The review of the literature in complementary therapy use, lacks studies conducted by nursing. More nursing research is needed in the area of complementary therapy use. The reason for this is twofold. First, nursing studies are vitally important so that nursing can be more informed of the common complementary therapies patients might be using. This is especially important to understand while the patient is undergoing chemotherapy because some of the therapies they may be practicing could be potentially detrimental during chemotherapy treatment. Second, additional nursing research in complementary therapy use would also be beneficial to patients as it may open communication between the patient and the nurse caring for them and allow patients to make informed decisions and impact the design of care. Last, further studies are needed to include both male and female chemotherapy patients. In this review, only one study included men receiving treatment in their study population (Sollner et al, 1997). Little

information is available on therapies that men may pursue during and after treatment. It is important to have an understanding the interests of both men and women in order to provide quality treatment to both populations.

## Chapter III

### Methods

This chapter describes the research methods that were utilized in this study. The sample and the instruments utilized for data collection are explained. The reliability and validity for the instrument are identified and summarized. Institutional approval, consent and data collection procedures as well as analysis of data are also explained.

#### *Sample*

The target sample consisted of 114 patients, 38 that were undergoing (a) chemotherapy, (b) 38 that were undergoing radiation, (c) 38 that were receiving a combination of chemotherapy and radiation therapy at the time of the survey. The subjects were recruited from a local veteran's hospital chemotherapy and radiation outpatient clinics. The eligibility criteria included a diagnosis of cancer for which the patient was receiving treatment, 18 years old or older, able to read and write English, able to sign consent and a veteran of the United States military service. Patients who were admitted to the hospital for treatment were excluded from the study because of limited access to specific complementary therapies due to confinement. Using power analytic techniques, it was estimated that a sample size of 114 was needed to detect a moderate effect size with power of .80 and alpha set at  $p = .05$ . The statistical data provided by the veterans hospital indicated that of the 447,000 outpatients served yearly, approximately 4% are women. Therefore, it was estimated that 14 of this sample would be women and

100 participants would be men. Due to the time constraints of this thesis, a convenience sample of 30 was obtained.

#### *Instrumentation*

##### *Complementary Therapy Rating Scale*

A modified questionnaire was used from a scale developed by Bennett and Lengacher (1998) to determine patterns of complementary therapy use and intent to use (Appendix A). Fourteen content areas are addressed. These areas include exercise, humor, hypnosis, massage, chiropractic, acupuncture, music therapy, prayer, relaxation therapy, vitamins, herbs/health foods, healthy diet and anticancer diet. Subjects were then asked to rate each item using a Likert scale ranging from 0 (I am currently doing this) to 4 (definitely would not try). In addition to this scale, there was a qualitative question asking the veteran to list any other information the subject might be using in addition to the other items listed. A total score was also determined by the sum of the subject's scores for each of the 14 items. A low overall score represents a high interest in the use of complementary therapies whereas a high score indicates a lower likelihood of interest and use of complementary therapies.

*Validity.* A doctoral clinical committee was created to formulate items for a pilot study conducted with rural midwestern cancer patients. The fourteen content area scales were determined and then validated by doctorally prepared nurses who were involved in complementary therapy research. These scales were also reviewed by oncology nurses and administrators for acceptability in the setting selected for the study and administrators from the various clinical testing sites.

*Reliability.* The reliability was reported using this instrument for the first time in 75 rural Midwestern cancer patients. Although this was the first study utilizing this tool, the alpha coefficient on the total score was .77. The reported internal consistency for this instrument was .86 using split-half reliability. This result allows this instrument to be considered reliable for future studies in this population.

#### *Demographic Data Form*

A demographic data form was included to assess general characteristics of the sample (Appendix B). These included gender, educational level, age, cancer type and length of diagnosis, race, area where they live and medical treatment they were currently receiving.

#### *Institutional Approval*

A copy of the proposal and a request for approval of this proposal was submitted to the James A. Haley Veteran's Medical Center Research and Development Committee, Tampa, Florida. Following that approval (Appendix C), an application was submitted and approved by the Institutional Review Board at the University of South Florida (Appendix D).

#### *Procedures*

The sample was obtained by visiting both the outpatient radiation and chemotherapy waiting and treatment rooms. An overview of the study and an outline of participant eligibility were presented to the staff with a request for assistance with patient referral. The patients were sampled while visiting the clinic during treatment for convenience. Prior to consent, an overview of the study was presented to the patient. Once the patient agreed to participate, an explanation of the study was presented

individually with each patient and a signed consent was obtained (Appendix E). After the consent was obtained, the questionnaire for complementary therapy was administered and returned in an unmarked envelope to the investigator. Strict confidentiality was maintained for each subject. A copy of the signed consent was given to the patient and a copy was placed in his or her outpatient file.

#### *Data Analysis*

The first research question asked 1) What are the types of complementary therapy used most frequently by veterans being treated for cancer? To answer this research question, each of the fourteen Likert scale items were analyzed using frequency and percent of each item identified. These statistics determined the number and percent of veterans using each therapy. The qualitative question results also were summarized.

The second question, 2) Is there a relationship between the use of complementary therapies and age or education in veterans being treated for cancer? Pearson correlations were used to determine if correlations existed between age or education and CTRS scores.

The third question, 3) What is the overall intent to use complementary therapies in veterans being treated for cancer? A total score for each individual was obtained. Mean and standard deviations were also computed.

## Chapter IV

### Results, Discussion and Conclusions

This chapter includes the results of this study. It begins with a description of the sample. A summary of the results are then described using the research questions as a guide. This is followed by a discussion of the findings of this study, and the section concludes with a brief summary statement of these findings.

#### *Results*

##### *Sample*

The sample consisted of 30 veterans, 29 males and one female. Education and length of time since diagnosis were rounded to the closest year. Those with a diagnosis less than one year were grouped in the one year category. Subjects were predominantly Caucasian (90%, n=27) with an average of 13.6 years of education and 3.0 years since diagnosis (Table 1). Forty – seven percent of the sample (n=14) had one or more years of college or post high school technical education.

Table 1

#### *Means, Standard Deviations and Ranges for Demographic Variables*

	Range	Mean	SD
Age	41-87 years	63.9	11.4
Years of Education	9-22 years	13.6	3.4
Time of diagnosis	1-30 years	3.0	6.0

Of the 30 sampled, twelve different cancer types were identified. The most predominant subset of the sample was prostate cancer at 33.3% (n=10) followed by lung cancer at 23.3% (n=7) (Table 2).

Table 2

*Frequency and Percent of Subjects by Type of Cancer*

Type of Cancer	Frequency	Percent
Prostate	10	33.3
Lung	7	23.3
Head and Neck	4	13.3
Colon/Rectal	4	13.3
Skin	1	3.3
Multiple Myeloma	1	3.3
Colon and prostate	1	3.3
Cervix	1	3.3
Polycythemia vera	1	3.3
Total	30	100

The predominant treatment group in the sample was radiation therapy patients at 63.3%, ( n=19). Smaller numbers were receiving other therapies or combinations (Table 3).

Table 3

*Frequency and Percent of Subjects by Medical Treatments Received*

Type of Treatment	Frequency	Percent
Radiation	19	63.3
Chemotherapy	5	16.7
Chemotherapy and radiation	5	16.7
Biotherapy	1	3.3

Area where the subjects reside was also requested in the demographic data. Subjects were about equally divided among urban, suburban, small town, and rural settings (Table 4).

Table 4

*Frequency and percent of Subjects by Type of Community*

Type of Community	Frequency	Percent
Urban	9	30%
Suburban	8	26.7%
Small town	7	23.3%
Rural	6	20%

### *Intent to Use Items*

The types of complementary therapy used most frequently included vitamins, with 76.7% (n=23) of the sample currently using at least one vitamin regularly. Vitamins were followed closely by both relaxing music and imagery and prayer for healing and pain relief at 70% (n=21). Conversely, none of the patients was currently undergoing hypnosis therapy during treatment. Massage was used by 13.3% (n=4), but 33.3% (n=10) of the sample stated that they definitely would try massage. Fourty-six point seven percent of the sample surveyed (n=14), stated they probably would not try group exercise (Table 5).

Table 5

*Frequency and Percent of Responses to Items on the Complementary Therapy Rating Scale*

Item	I am currently doing this		Definitely would try		Probably would try		Probably would not try		Definitely would not try	
	f	%	f	%	f	%	f	%	f	%
Taking vitamins on a regular basis	23	76.7	3	10	2	6.7	0	-	2	6.7
Listening to relaxing music and visualizing pleasant things	21	70	3	10	2	6.7	1	3.3	3	10
Prayer for healing and pain relief	21	70	3	10	1	3.3	2	6.7	3	10
Use of humor, (funny movies or books); making a joke of the situation	17	56.7	5	16.7	3	10	0	-	5	16.7
Changing your diet to include more healthy foods	11	36.7	7	23.3	5	16.7	3	10	4	13.3
Taking herbs or other health food items	11	36.7	3	10	5	16.7	2	6.7	9	30
Going on a strict “anti-cancer diet”	6	20	7	23.3	4	13.3	4	13.3	9	30
Going to chiropractor	6	20	5	16.7	3	10	3	10	13	43.3
Professional massage	4	13.3	10	33.3	4	13.3	1	3.3	10	33.3
Attending a regular exercise group	4	13.3	4	13.3	4	13.3	14	46.7	4	13.3
Going to a support group	2	6.7	6	20	8	26.7	2	6.7	12	40
Going to a relaxation treatment group	2	6.7	4	13.3	8	26.7	4	13.3	12	40
Acupuncture treatment	1	3.3	4	13.3	4	13.3	6	20	15	50
Professional hypnosis	0	-	4	13.3	4	13.3	6	20	16	53.3

### *Current Patterns of Use*

Most patients were using more than one type of complimentary therapy. Only one of the patients was not using any therapies. The rest of the sample utilized one or more. The highest number of therapies being used concurrently in this sample was nine (n=1) (Table 6).

Table 6

### *Current Patterns of Use*

Amount of therapies	Frequency	Percent
zero	1	3.3%
one	2	6.7%
two	2	6.7%
three	7	23.3%
four	5	16.7%
five	4	13.3%
six	4	13.3%
seven	3	10%
eight	1	3.3%
nine	1	3.3%
Total	30	100%

### *Relationships with Demographic Variables*

Pearson correlations revealed significant relationships between persons with higher education and the use of prayer, ( $r = -.406, p = .029$ ), vitamins  $r = (-.448, p = .013)$  and herbs ( $r = -.394, .035$ ). Increased age indicated a decrease in the likelihood of using hypnosis as complementary therapy ( $r = .396, p = .030$ ). This was the only item that was found to be significantly related to age.

### *Overall Intent Scores*

The lowest possible total score for the intent scale was 0 which indicated definite use of all variables listed. The highest possible score for the scale is 56. This score would indicate no usage or intent to try any of the variables listed in the scale. The lowest score for our sample was 11, indicating a high percentage of usage or likelihood to use complementary therapies. The highest score for the present sample was 55, indicating low to no interest in the use of the complementary therapy items listed. The range therefore was 11-55 with the mean score of 26.5 and a standard deviation of 11.1.

### *Other Findings*

In addition to these results, there were several items listed in response to the qualitative question about other therapies. The survey question asked the participant to list any complementary therapies they currently are using that were not listed on the survey. Several participants listed more than one therapy was important during their therapy. The frequency and type of responses are listed in Table 7.

Table 7

*Other Complementary Therapies Identified*

Therapy Identified	Frequency of Times Identified
Individual exercise (includes walking)	8
Sports including golf, bowling, fishing, billiards, horses, hunting	6
Crafts/crossword/puzzles/collecting or	4
Automotive	
Spousal support	4
Family or friend support	3
House work	2
Positive attitude	2
Yard work	1
Meditation	1
Laryngectomy society	1

*Discussion*

*Sample*

A major limitation of this study was the small sample size. One of the participants mistakenly forgot to answer a question on massage. Because of the small sample, the omission could have changed the results of the massage responses that may potentially have resulted in some correlation changes. In addition, the study was a convenience sample that was obtained during a limited number of days over a period of only a few weeks.

There was some difficulty in recruiting chemotherapy patients to participate in the study. That ultimately lead to an unequal number of participants receiving each type of treatment. The chemotherapy patients refused to participate more often than the radiation patients did. Perhaps this was due to more treatment side effects or a decreased sense of wellness or increased fatigue. This refusal might have biased the results in some manner.

The sample was not equally representative of both men (n=29) and women (n=1) as there were fewer women to survey in the veteran group. This could be an identified limitation. However, one of the benefits of this study is the larger population of men in the sample. Because there are limited studies on the usage of complementary therapy in men, this study identified some issues that may require a critical analysis of the current tools. For example, when research subjects were asked if they would participate in group exercise, 46.7% stated they probably would not. Yet, these same men reported that they exercise alone daily and felt it was a critical part of their cancer treatment. The questionnaire identified exercise in groups but did not identify individual exercise as a possible choice. Further, four of the subjects surveyed stated that they would definitely not attend a support group. However, they listed items such as a music group, the laryngectomy society, car clubs and bowling leagues as other complementary therapies used. This offers possible insight into why support groups for men are generally less successful than for women. These results may suggest the need for further exploration to define ideas and feelings about group activities and how they are viewed. A limitation to the study was that it was not ethnically balanced but was heavily Caucasian. The study was also limited to veterans in one hospital treatment facility at the exclusion of veterans

who receive treatment in private offices or in other veterans treatment facilities around the country.

#### *Intent to Use Scores*

One of the limitations of the questionnaire was that it did not address was the participants prior use of a particular therapy. This could be important in differentiating whether there was no interest in that therapy or whether they would definitely not try a therapy based on prior experience. One of the common responses to the survey was that they had tried an item previously, but were not currently using it. It would be interesting to identify what they had used in the past and whether that had any effect on what they would be more likely to try in the future.

One of the major benefits of the study is that it presents some further insight into the prevalence of use and interest in complementary therapies. The results of the intent to use scale demonstrate the prevalence of these therapies in patients who are undergoing treatment for cancer.

#### *Relationships with Demographic Variables*

Results of this study, did show a statistical significance that occurred between having a higher education and an increased likelihood to use prayer ( $r = -.406$ ,  $p = .029$ ). Perhaps this was specific to this sample or to a veteran population. Of note in this study, was the high percentage of participants with post high school education. In fact, 14 of 30 participants had some post high school college or trade school and six of the sample had 18 years or more of education. Further research is needed to identify whether a relationship does exist between education and prayer. In contrast, the relationship between higher education and the use of complementary therapy (Allen et al., 1997;

Crocetti et al., 1998; Fernandez et al., 1998; Risberg et al., 1997) reported in the literature, was again noted in this sample. Most notable was the use of vitamins ( $r = -.448$ ,  $p = .013$ ), and herbs ( $r = -.394$ ,  $p = .035$ ) among better educated patients.

#### *Overall Intent Scores*

The overall usage scores demonstrate an increased likelihood of patients using one or more therapies concurrently during treatment ( $n=29$ ). This may be attributable to increased media and advertising of items such as vitamins and herbal preparations. This may also be attributed to easy access to these therapies. Ajzen (1980) theorized that behavioral control was related to a person's perception of how difficult or easily the behavior could be performed. Perhaps multi therapy use is a combination of interest, access and how the act is viewed by themselves or others. This study identifies frequent use of music, vitamins and prayer. These are items are generally well publicized, readily accessible and may be considered traditional and therefore permissible by families. This is compared to the lower scoring items such as support groups, acupuncture or chiropractic services. These items are not generally as accessible (usually practiced outside the home) and may not be as well received by family members.

#### *Other Findings*

Other complementary therapies identified were diverse and perhaps gender dominant. Men reported other therapies such as hobbies, sports, family and friend support and support for their spouses as therapies they were using or would like to try. Sports and exercise were the most frequently described methods of what participants considered complementary therapies for them. This may be associated with their interests prior to the cancer diagnosis or possibly lifetime habits and hobbies. According to the theory of

planned behavior by Azjen (1980), one sample of a person's behavior is a really a culmination of influences that the individual has experienced in other situations or occasions. An individual may have historically relied on sports, hobbies and exercise, whether emotional or physical, to relieve stress. These behaviors may then naturally occur when a stress such as the diagnosis of cancer is introduced and may account for any gender differences identified in this survey question.

One limitation of this study was that it did not clearly define complementary therapies when asking what other complementary therapies not listed were used. This clarification may be important as considerable overlap could exist in the participants' definition of complementary therapies and coping. Some of the complementary therapies that the study participants listed may be considered coping behaviors versus therapies used to complement conventional treatment. An unexpected response to the other therapies used question was among the four participants who expressed a strong desire for spousal support. This may suggest that their feelings of well being are somehow affected by the coping of their spouse. Possibly, they feel that if their spouse has good support, they won't need to worry if something should happen to them. Perhaps they feel that they receive better caring from their spouse if the spouse is better cared for.

The results of this study identify a significant number of implications for the oncology nurse. It identifies some insight into the use of complementary therapy use in men. It has also identified some issues that may be unique to this veteran population. Identifying the complementary therapies that a patient employs in conjunction with their treatment is paramount to the oncology nurse. The use of complementary therapy can have significant implications, important in regard to side effects, research, quality of life,

survival and drug interactions. It is also important for the nurse not only to identify these but also to understand that their usage is usually not limited to one therapy. In addition, it is vital for the nurse to understand what is therapeutic from the patient perspective. When choosing a therapy for a male patient, group activities for support and exercise may not be as effective as other therapies. This study addresses that issue and provides possible alternatives through the survey results. Perhaps the use of music could be introduced into the clinic setting. Massage is another possibility. There was 13.3% of the sample currently using massage, yet 33.3% stated they definitely would try. Nurse's awareness of the complementary therapies used and the interest in usage is important to provide accurate and up to date information as well as provide for cost effective, holistic care and patient support in the clinical setting.

### *Conclusions*

This study provided an overview of the most frequently used complementary therapies in a veteran population. A larger study is needed to further identify the usage and intent in this population. Further, more gender specific studies are needed to develop questionnaires and to identify whether patterns of use and intent differ between men and women. The CTRS questionnaire could be reviewed and modified to include individual activities and more gender specific questions regarding sports and hobbies. Other modifications to the questionnaire for future studies could include a quality of life and a fatigue scale. This may provide some insight into the impact of fatigue or decreased quality of life on a person's complementary therapy use. In addition, the survey could include a question on prior use of a given therapy to differentiate between no interest and perceived effects. The use of vitamins and herbs during treatment could be an individual

topic for research, because many of the patients were using more than one type of supplement during their treatment. Linked to the intent to use scale is the question that focuses on why a person with cancer engages in complementary therapy use. This research question could investigate whether a relationship exists between the individual's locus of control and the use of complementary therapies or perhaps Azjen's theory of planned behavior. Finally, further investigation is needed to explore the importance of spousal support in a person undergoing treatment for cancer.

## References

Ajzen, I. F., M. (1980). *Understanding Attitudes and predicting social behavior*. Englewood Cliffs, NJ: Prentice-Hall.

American Cancer Society (1999). Cancer, facts and figures. Atlanta, GA: American Cancer Society.

Bennett, M., & Lengacher, C. (1998). Design and testing of a complementary rating scale in rural persons with cancer. *Alternative Health Care Practitioner*, 4\_(3), 179-198.

Bennett, M. & Lengacher, C. (1999). Use of complementary therapies in a rural cancer population. *Oncology Nursing Forum*, 26 (8), 1287-1294.

Brigden, M. (1995). Unproven (questionable) cancer therapies. *Western Journal of Medicine*, 163, 463-469.

Brown, P., & Carney, P. (1996). Health beliefs and alternative medicine: qualitative study of breast cancer patients. *Journal of Cancer Education*, 11(4), 226-229.

Cassileth, B., & Chapman, B.A. (1996). Alternative cancer medicine: A ten year update. *Cancer Investigation*, 14(4), 396-404.

Crocetti, E., Crotti, N., Feltrin, A., Ponton, P., Geddes, M., & Buiatti, E. (1998). The use of complementary therapies by breast cancer patients attending conventional treatment. *European Journal of Cancer*, 34(3), 324-328.

Eisenberg, D., Kessler, R., Foster, C., Norlock, F., Calkins, D., & DelBanco, T. (1993). Unconventional Medicine in the United States. *The New England Journal of Medicine*, 338, 246-252.

Fernandez, C., Stutzer, C., MacWilliam, L., & Fryer, C. (1998). Alternative and complementary therapy in pediatric oncology patients in British Columbia: Prevalence and reasons for use and nonuse. *Journal of Clinical Oncology*, 16(4), 1279-1286.

George, J.(Ed.) . (1985). *Nursing Theories; The Base for Professional Nursing Practice*, (2<sup>nd</sup> ed.). Englewood Cliffs, New Jersey: Prentice-Hall, Inc.

Gray, R., Greenberg, M., Fitch, M., Voros, P., Chart, P., Labrecque, M., Douglas, M., & Parry, N. (1998). A strategy for informing patients and health professionals about unconventional therapies. *Journal of Cancer Education*, 13(1), 31-38.

Herbert, C., (1997). Can primary physicians be a resource to their patients in decisions regarding alternative and complementary therapies for cancer? *Patient Education and Counseling*, 31, 179-180.

Lerner, I., & Kennedy, B. (1992). The Prevalence of questionable methods of cancer treatment in the United States. *CA: A Cancer Journal for Clinicians*, 42, 181-191.

Risberg, T., Bremnes, R.M., Wist, E., Kaasa, S., & Jacobsen, B.K. (1997). Communicating with and treating cancer patients: How does the use of non-proven therapies and patients' feeling of mental distress influence the interaction between the patient and hospital staff. *European Journal of Cancer*, 33(6), 883-890.

Risberg, T., Kaasa, S., Wist, E., & Melsom, H. (1997). Why are cancer patients using non-proven complementary therapies? A cross-sectional multicenter study in Norway. *European Journal of Cancer*, 33(4), 575-580.

Risberg, T., Lund, E., Wist, E., Kaasa, S., & Wilsgaard, T. (1998). Cancer patients use of nonproven therapy: A 5-year follow-up study. *Journal of Clinical Oncology*, 16(1), 6-12.

Risberg, T., Wist, E., & Bremnes, R.M. (1998). Patient's opinion and use of non-proven therapies related to their view on cancer aetiology. *Anticancer Research*, 18, 499-506.

Sollner, W., Zingg-Schir, M., Rumpold, G., & Fritsch, P. (1997). Attitude toward alternative therapy, compliance with standard treatment, and need for emotional support in patients with Melanoma. *Archives of Dermatology*, 133, 316-321.

Spaulding-Albright, N. (1997). A review of some herbal and related products commonly used in cancer patients. *Journal of the American Dietetic Association*, 97(10), supp.2, 208-215.

Spiegel, D., Stroud, P., & Fyfe, A. (1998). Complementary medicine. *Western Journal of Medicine*, 168(4), 241-247.

Stromberg, M., & Olsen (1997). *Instruments for Clinical Health-Care Research*, (2<sup>nd</sup> ed.). Sudbury, Massachusetts: Jones and Bartlett.

Swanson, S., & Facione, N. (1998). Complementary and alternative medicine practices in women with breast cancer. *American Journal of Nursing*, supplement April, 34-39.

## Appendices

## Appendix A: Complementary Therapy Rating Scale

### Complementary Therapy Rating Scale 24

The chart below contains items which some people use to help themselves cope with cancer symptoms, cancer treatment, depression, or just to help themselves live a more healthy lifestyle. I am very interested in which of these things you would be interested in trying, or are currently doing. Please circle the number which best indicates how you feel about trying each particular activity.

#### Use and Intent Subscale

	I am currently doing this	Definitely would try	Probably would try	Probably would not try	Definitely would not try
Attending a regular exercise group	0	1	2	3	4
Use of humor, (funny movies or books); making a joke of your situation	0	1	2	3	4
Professional hypnosis	0	1	2	3	4
Professional massage	0	1	2	3	4
Going to a chiropractor	0	1	2	3	4
Acupuncture treatment	0	1	2	3	4
Listening to relaxing music and visualizing pleasant things	0	1	2	3	4
Prayer for healing or pain relief	0	1	2	3	4
Going to a relaxation treatment group	0	1	2	3	4
Taking regular vitamins on a daily basis	0	1	2	3	4
Taking herbs or other health food items	0	1	2	3	4
Changing your diet to include more healthy foods	0	1	2	3	4
Going on a strict "anti-cancer diet"	0	1	2	3	4
Going to a support group	0	1	2	3	4

#### **Appendix A (continued)**

The items on the previous page were chosen from numerous activities which some people with cancer have tried to help themselves feel better. If you are doing anything to help yourself which was not on this survey, or would be interested in a treatment/activity which was not on this survey, please write a few lines in the space below which describes this activity.

**Appendix B: Demographic Data Form**  
**COMPLEMENTARY THERAPY RATING SCALE**

The following questions tell us something about your general background and some basic information about your medical condition.

---

Sex    M    F

Number of years of education? \_\_\_\_\_

Type of Cancer \_\_\_\_\_

Age \_\_\_\_\_

How long have you known that you have cancer?

---

---

Race:

Caucasian non-Hispanic

Hispanic

African Descent

Asian Descent

American Indian

Other

---

Area where you live:

Urban

Suburban

Small town

Rural

---

Medical Treatments you are currently receiving:

(Please circle)

Chemotherapy

Radiation treatment

Chemotherapy and radiation together

Other- please describe

No medical treatment at this time

Please continue on the next page:

Appendix C: Veteran's Administration Approval letter

Department of  
Veterans Affairs

Memorandum

Date: January 18, 2000  
From: Associate Chief of Staff for Research & Development (151)  
Subj: Review of Research Protocol  
To: Sandra Holley, RN, Ph.D. (118)

1. Your research proposal titled "Use of Complementary Therapies in Persons Receiving Treatment for Cancer" was reviewed by the Research & Development Committee on Friday, December 3, 1999. The Committee approved the proposal pending modification of the Informed Consent, clarification of a reference and recalculating the sample size. All the concerns of the committee have been appropriately addressed, therefore approval of your research proposal is granted.
2. **Full approval of the research proposal is contingent upon receipt of documentation in the Research Office (151) from the USF Health Sciences IRB that the Informed Consent was reviewed and approved. Once full approval is granted, patients may then be admitted to the study.**
3. The R&D Committee requires that each person agreeing to be a subject in an approved human studies protocol certify to the Committee, in writing, that all aspects of the Informed Consent have been met at the time of his/her enrollment in the study. This approval proviso is satisfied by having each subject complete, sign, and through you, send the original copy of the Memorandum of Certification to the Research Office (151).
4. VA regulations require that the original signed consent form must remain in the patient's chart and copies must be retained in the experimental/research file under conditions of confidentiality (M-3, Part 1, Chapter 9.11, b. (1)). In addition, FDA requires that in the case histories (i.e., progress notes, clinic notes, etc.) it be documented that the informed consent was obtained and that it was prior to participation in the study (21 CFR Parts 50, 312 and 812).
5. If modification(s) in the protocol or consent form is(are) required, please submit four copies of the revisions to the Research Office for review and approval.



ROBERT V. FARESE, M.D.

## Appendix D: IRB Approval Letter



February 1, 2000

Sandra Holley, PhD, ARNP, AOCN  
C/O Rose M. Bell, RN, BSN, OCN  
Department of Nursing  
MDC Box 22

Dear Dr. Holley:

Your new protocol (IRB #98.851) entitled,

**"The Use of Complementary Therapies in Persons Receiving Treatment for Cancer"**

including the Adult Informed Consent has been approved under expedited review category number seven. This information shall be presented to the Institutional Review Board-02 at its next convened meeting on February 18, 2000. You should take special note of the following:

- Approval is for up to a twelve-month period. A Research Progress Report to request renewed approval must be submitted to this office **by the submission deadline in the eleventh month of this approval period**. A final report must be submitted if the study was never initiated, or you or the sponsor closed the study.
- Any changes in the above referenced study may not be initiated without IRB approval except in the event of a life-threatening situation where there has not been sufficient time to obtain IRB approval.
- All emergency uses of a test article must be reported to the IRB within five (5) working days of occurrence.
- All changes in the protocol and informed consent must be reported to the IRB.
- If there are any adverse events, the Chairperson of the IRB must be notified immediately in writing.

If you have any questions regarding this matter please do not hesitate to call me at 974-5638.

Sincerely,

A handwritten signature of Mary K. Walker.

Mary K. Walker, Ph.D.  
Chairperson, IRB-02

APPROVED THRU
JAN 2001
USF-C2 INSTITUTIONAL REVIEW BOARD M-1284-02XV

MKW: amr  
cc: FAO  
cc: JAH-VA

Submit your Research Progress Report by the submission deadline **one month prior to the above date**. Failure to meet this deadline will result in closure of this study.

**Office of Research, Division of Compliance Services  
Institutional Review Boards, MPA No. 1284-01/M1284-02XM**  
University of South Florida • 12901 Bruce B. Downs Blvd. MDC 035 • Tampa, Florida 33612-4799  
(813) 974-5638 • Fax (813) 974-5618

Rev2.98 I:\Letters.Expedited

The University of South Florida is an Affirmative Action/Equal Access/Equal Opportunity Institution

## Appendix E: Consent Form

### Social Sciences/Behavioral Adult Informed Consent

University of South Florida

#### Information for People Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to be a part of a minimal risk research study. Please read carefully. If you do not understand anything, ask the Person in Charge of the Study.

<b>Title of Study:</b>	The Use of Complementary Therapies in Persons Receiving Treatment for Cancer
<b>Principal Investigator:</b>	Sandra Holley Ph.D., ARNP, AOCN
<b>Person in Charge of the Study:</b>	Rose M. Bell RN, BSN, OCN, USF NP student
<b>Co-Investigator(s):</b>	Rose M. Bell
<b>Study Location(s):</b>	James A. Haley Veterans Hospital, Tampa, Florida

You are being asked to participate because we are interested in expanding the nurse's knowledge of complementary therapy used by persons undergoing treatment for cancer.

#### General Information about the Research Study

The purpose of this study is to identify the prevalence of use or interest in using complementary therapies in persons undergoing treatment for cancer.

The number of people who might take part in this study is: 114 patients who are currently receiving radiation therapy, radiation and chemotherapy or chemotherapy alone for the medical treatment of cancer.

#### Plan of Study

- You will be asked to complete a questionnaire consisting of Demographic data and a survey of use and intent to use complementary therapies. This study takes approximately 10 minutes or less to complete.

#### Benefits of Being a Part of this Research Study

- There are no direct benefits to you for participation. However, by taking part in this research, you will be contributing to the nurse's awareness of the most current and common complementary therapies used, as well as who is most likely to be interested in its usage. This information is important so nurses can provide accurate, honest information and the best nursing and overall care for each individual patient.

#### Risks of Being a Part of this Research Study

- There is no known psychological or social risk for your participation in this study.

#### Alternatives of Being Part of this Research Study

- You may choose not to participate

APPROVED THRU	
JAN 2001	
USF-02 INSTITUTIONAL REVIEW BOARD M:1284-0204	

1

## Appendix E (continued)

### Confidentiality of Your Records

- Your privacy and research records will be kept confidential to the extent of the law. Each subject will be coded using a consecutive number according to the therapy you receive. Access to these records is limited to the research office, the investigator in charge of the study and the principal investigator. The data will be kept in a locked file cabinet in my office and the VA research office. Authorized research investigators, agents of the Department of Health and Human Services and the USF Institutional Review Board may inspect your records from this research project.
- The results of the study may be published in grouped form. In other words, the published results will not include your name or any other information that will identify you.

### Payment for Participation

You will be responsible only for the costs you normally incur for health care services provided by the James A Haley VA. You will not receive any payment for your participation in this study. You will not incur additional health care costs by agreeing to participate in this study.

### Volunteering to Be Part of this Research Study

- Your decision to participate in this research study is completely voluntary. You are free to participate in this research study or to withdraw at any time. If you choose not to participate, or if you withdraw, there will be no penalty or loss of benefits that you are entitled to receive.

### INJURY RESULTING FROM THIS RESEARCH

If you have any medical problems as a result of participating in this study at the James A. Haley Veterans' Hospital, the VA will provide emergency care.

### Questions and Contacts

- If you have any questions about this research study, contact Sandra Holley at the James A. Haley Veterans Hospital (813) 972-2000 ext. 3997.
- If you have questions about your rights as a person who is taking part in a research study, you may contact a member of the Division of Compliance Services of the University of South Florida at 813-974-5638.

### Your Consent—By signing this form I agree that:

- I have fully read or have had read and explained to me in my native language this informed consent form describing a research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to participate in research. I understand the benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.

---

Signature of Participant

Printed Name of Participant

Date

I have carefully explained to the subject the nature of the above protocol. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study and that a medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in this study.

---

Signature of Investigator

Printed Name of Investigator

Date

APPROVED THRU	
JAN 2001	
USF-02 INSTITUTIONAL REVIEW BOARD M-1264-020X	

2

## Appendix E (continued)

### Institutional Approval of Study and Informed Consent

This research project/study and informed consent form were reviewed and approved by the University of South Florida Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at (813) 974-5638.

Approval Consent Form Expiration Date:

Revision Date: \_\_\_\_\_

